



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,816	04/30/2001	Paul F. Corey	MSE #2609	3320

7590 05/02/2003
toby kusmer
mcdermott wil & emery
28 state street
boston, MA 02109

EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
----------	--------------

1621

DATE MAILED: 05/02/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/844,816

Applicant(s)

COREY ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 42-44 is/are objected to.
- 8) ☒ Claim(s) 1-11 and 42-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>Z</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicants' election without traverse of Group I, claims 1-11 in Paper No. 3 is acknowledged. Applicant's election of species, with traverse, in Paper No. 3, is acknowledged. Applicants have elected the specie with the following selection of variable group identities: R_1 = arenesulfonyl, R_2 = NO_2 , R_3 =phenylpyrrole which corresponds to the compound of Example 4 on pages 17-20 of the specification.

Applicants traverse the election of species requirement on the basis that limiting the identities of the variable groups R_1 and R_2 creates a small enough subgenus to represent a reasonable number of species and that therefore R_3 should not be limited beyond the "aryl" group already claimed.

The Examiner disagrees. Applicants' definition of aryl as set forth in the specification (Page 5, lines 13-23) includes 5-15 membered monocyclic or fused polycyclic systems containing 0-4 oxygen, sulfur or nitrogen atoms. Thus the designation "aryl" contains a vast number of possible structure spanning a large number of classifications. The search of all the various possibilities would clearly represent a burdensome search. The election of species requirement is therefore deemed justified by the Examiner and is maintained.

Specification

2. The abstract of the disclosure is objected to because a) there appears to be an extraneous "(l)" on line 2 and b) the structure should be presented on a line of its own without text. Correction is required. See MPEP § 608.01(b).
3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "R₃ comprises a heterocyclic aromatic moiety". It is unclear what else the limitation "comprises" encompasses. It is therefore impossible to determine the scope of claim 6 and it is therefore rendered indefinite.
5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "R₃ is 1-naphthol". There is insufficient antecedent basis for this limitation in the claim. Claim 9 is therefore

Art Unit: 1621

rendered indefinite. NOTE: It is unclear whether Applicants intend to claim the naphthyl peroxyester produced by this selection for R₃. The Examiner believes that Applicants intend instead that "R₃ is 1-naphthyl".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray et al (Enzyme Microb. Technol. 1983, 5, pages 137-142). Gray discloses (Page 140, column 1, line 1- column 2, line 7) the synthesis of 4-methylumbelliferyl α -N-benzoyl-N^G-nitroarginate which corresponds to a claimed compound of the invention wherein R₁= benzoyl (an acyl group), R₂= NO₂, R₃= a coumarin nucleus (fused polycyclic heteroaromatic). Gray further discloses (Page 139, column 1, lines 33-33) the synthesis of 2-naphthyl- α -N-benzoyl-N^G-nitroarginate which corresponds to a claimed compound of the invention wherein R₁= benzoyl (an acyl group), R₂= NO₂, R₃= a naphthalene nucleus (fused polycyclic carbocyclic aromatic). Gray discloses (Page 137, column 1, lines 1-6) 4-methylumbelliferone is optically distinct from its esters. Claims 1-8, 10 and 11 are therefore anticipated by Gray.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al (Enzyme Microb. Technol. 1983, 5, pages 137-142) and further in view of Aldrich (Aldrich Catalog Handbook of Fine Chemicals, 1994, Milwaukee, WI, page 1020).

Instantly claimed are compounds of formula (I) where R_1 and, R_2 are protecting groups, R_3 is an aryl group. Also claimed are the compounds wherein R_3 is a 2-naphthyl group.

Gray teaches (Page 140, column 1, line 1- column 2, line 7) the synthesis of 4-methylumbelliferyl α -N-benzoyl- N^G -nitroarginate which corresponds to a claimed compound of the invention wherein R_1 = benzoyl (an acyl group), R_2 = NO_2 , R_3 = a coumarin nucleus (fused polycyclic heteroaromatic). Gray further teaches (Page 139,

Art Unit: 1621

column 1, lines 33-33) the synthesis of 2-naphthyl- α -N-benzoyl-N^G-nitroarginate which corresponds to a claimed compound of the invention wherein R₁= benzoyl (an acyl group), R₂= NO₂, R₃= a naphthalene nucleus (fused polycyclic carbocyclic aromatic). Gray teaches (Page 137, column 1, lines 1-6) 4-methylumbelliferone is optically distinct from its esters.

The difference between the compounds taught and those instantly claimed is that while Gray exemplifies the compound in which the variable R₃ has the identity 2-naphthyl, Gray does not suggest replacing it with the 1-naphthyl group.

Aldrich, however, teaches (Page 1020, lines 22-27) that 2-naphthol is lightsensitive while the corresponding 1-naphthol is not. This would have motivated one of ordinary skill in the art to replace the 2-naphthyl ester with the corresponding isomeric 1-naphthyl ester in the photometric method of Gray since it is clearly beneficial to have an analyte that is stable under the photometric conditions of measurement of the method of Gray. The two naphthyl esters are positional isomers about an aromatic nucleus they are therefore *prima facie* obvious over each other. One of ordinary skill in the art would therefore expect compounds which are so closely related in structure to exhibit similar properties

Thus the instantly claimed compounds would have been obvious to one of ordinary skill in the art. Because the two naphthyl esters are positional isomers about an

Art Unit: 1621

aromatic nucleus there would have been a reasonable expectation of success since one of ordinary skill would have expected them to exhibit similar properties.

Claim Objections

8. Claims 42 – 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. **NOTE:** The second claim 42 has been renumbered to claim 44 according to Rule 126.

Allowable Subject Matter

9. Claims 42-44 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art of record Gray et al (Enzyme Microb. Technol. 1983, 5, pages 137-142) and Aldrich (Aldrich Catalog Handbook of Fine Chemicals, 1994, Milwaukee, WI, page 1020) neither alone nor in combination disclose or fairly suggest the instantly claimed compounds in which R_1 = arenesulfonyl, R_2 = NO_2 and R_3 = phenylpyrrole.

Conclusion

10. Claims 1-11 and 42-44 are pending. Claims 1-11 are rejected. Claims 42-44 are objected to.

Art Unit: 1621

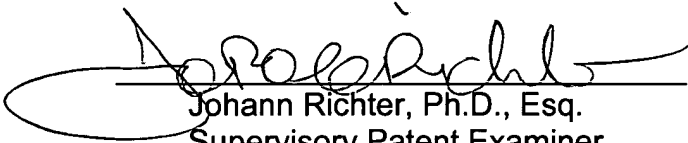
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker
Patent Examiner
Technology Center 1600

May 1, 2003



Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600